



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 13, 2020

Meghan Shoun
Regulatory Affairs Specialist
Spartan Chemical Company, Inc.
1110 Spartan Drive
Maumee, OH 43537

Subject: Label Amendment: Emerging Viral Pathogens
Claim Product Name: Tumult
EPA Registration Number: 5741-28
Application Date: March 10, 2020
Decision Number: 560831

Dear Ms. Shoun:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

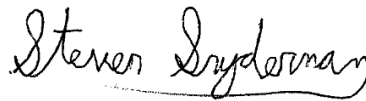
2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
 - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
 - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
 - A. CDC Current Outbreak List for “U.S. Based Outbreaks” (www.cdc.gov/outbreaks),
 - B. CDC Current Outbreak List for “Outbreaks Affecting International Travelers” with an “Alert” or “Advisory” classification (www.cdc.gov/outbreaks) (also released through the CDC’s Health Alert Network (HAN) notification process)
 - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
 - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI).
 - A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup is small non-enveloped, large non-enveloped, and enveloped.
 - B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE’s publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Feline Calicivirus (surrogate for Norovirus) and/or Poliovirus Type 1 is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact the disinfectants list at disinfectantslist@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Steven Snyderman". The signature is written in a cursive, flowing style.

Steven Snyderman, Acting Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: stamped label

Front Panel Copy:

Tumult

[RTU Bleach Disinfectant]

[Multipurpose] [Broad spectrum] [Hospital] [Healthcare]

[Cleaner Disinfectant with Bleach] [Cleans, Disinfects, Deodorizes, Virucidal*]

[Bactericidal]

[RTU Handi Spray]

[Kills spores of Clostridium difficile on hard, non-porous surfaces.]

ACTIVE INGREDIENT:

Sodium hypochlorite..... 0.74%

INERT INGREDIENTS: 99.26%

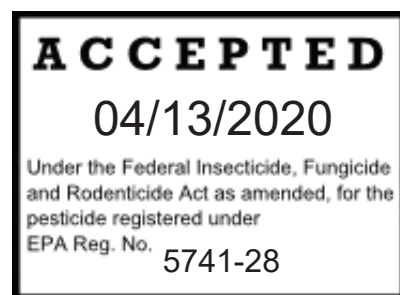
Total 100.00%

[Available Chlorine 0.70%]

[7000 PPM [Parts Per Million] Available Chlorine]

EPA Reg. No. 5741-28

EPA Est. No. 5741-OH-1



KEEP OUT OF REACH OF CHILDREN

CAUTION

See side [back] panel[s] for additional precautionary statements [and first aid]

SPARTAN CHEMICAL COMPANY, INC., 1110 Spartan Drive, Maumee, Ohio 43537
1-800-537-8990 /www.spartanchemical.com

NET CONTENTS:

Back Panel Copy:

This product [product name] is a [broad spectrum] [multipurpose][hospital] [healthcare] cleaner disinfectant which can be used in many areas [including] [such as]: (Insert **Use Site** selection)[and other] (Insert **Use Site** selection).

[This product] [product name] may be used to clean and disinfect [hard nonporous surfaces] [such as] (Insert **Objects** selection) [,][and] (Insert **Objects** selection).

[This product] [product name] can be used on surfaces made of (Insert **Materials** selection)

Note: This product may discolor or otherwise damage colored fabric, clothing, metal trim, electronic devices/components or other surfaces which could be harmed by sodium hypochlorite. Check manufacturer's cleaning and disinfection recommendations before use on equipment surfaces.

This product [product name] has been proven to be effective against the following pathogenic microorganisms on hard nonporous surfaces:

Bactericidal Activity -30 Second contact time with 5% blood serum:

- Escherichia coli, extended beta-lactamase resistant [(ESBL)] [(ATCC BAA-196)]
- Acinetobacter baumannii [(ATCC 19606)]

Bactericidal Activity -60 Second contact time with 5% blood serum:

- Staphylococcus aureus [(ATCC 6538)]
- Pseudomonas aeruginosa [(ATCC 15442)]
- Staphylococcus aureus, methicillin resistant [(MSRA)] [(ATCC 33592)]

Bacteria Sporicidal Activity- 8 Minute contact time:

- Clostridium difficile, spore form [(ATCC 43598)]

See Special Instructions for Cleaning Prior to Disinfection against Clostridium difficile spores

***Virucidal Activity- 30 second contact time with 5% blood serum:**

- Hepatitis A Virus [(Strain HM-175)]
- Hepatitis B Virus [(Hepadnavirus Testing, Inc.)]
- Hepatitis C Virus [(Bovine Viral Diarrhea Virus (BVDV) Oregon C24v-genotype 1 Strain)]
- Poliovirus Type 1 [(ATCC VR-1562, Strain Chat)]
- Norovirus [(Norwalk virus)]
- Feline Calicivirus [(ATCC VR-782)]
- Rotavirus [(Strain WA)] -Influenza A [(H1N1)] Virus [(ATCC VR-1469, Strain A/PR/8/34)]
- HIV Type 1 [(HIV-1)] [(Strain HTLV-III)]
- Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu).
- Kills Pandemic 2009 H1N1 influenza A virus.

(Note to EPA: [Bracketed] words & statements are optional unless specified in 40 CFR 156.10)

(List of **Use Sites:**

Covers Medical/ General / Veterinary / Food Processing / Hospitality and Lodging / Education)

Hospitals

Nursing homes

Healthcare settings

Healthcare facilities

Doctor's offices

Patient care rooms

Patient care areas

Rest homes

Long term healthcare facilities

Acute healthcare facilities Hospice facilities

Surgery rooms

Operating rooms

Office buildings

Offices

Schools

Hotels

Athletic facilities

Recreational facilities

Lodging establishments

Hospitality establishments

Any public place with restroom facilities

Veterinarian offices

Veterinary clinics

Kennels

Catteries

Animal hospitals

Animal hospital facilities

Animal care facilities

Pet care areas

Kitchens

Restaurants

Cafes

Cafeterias

Food processing facilities

Food preparation areas

Bars

Cruise ships

Jails

(Note to EPA: [Bracketed] words & statements are optional unless specified in 40 CFR 156.10)

Prisons
Correctional Facilities
Correction Facilities

(List of **Objects:** Within Medical/ General / Veterinary / Food Processing / Hospitality and Lodging / Education / Correctional Facilities Use Sites)

Bed railings
Bed frame
TV remote
Bedside table
Telephone
Chair arm
Exam tables
Examination table
Examination room
Blood pressure cuff
IV Poll
High touch surfaces
Critical touch points
Bedpans
Floors
Walls
Countertops
Tables
Table tops
Door knobs
Light switch
Waste receptacles
Trash can
Showers
Shower stalls
Shower handles
Shower head
Faucets
Urinals (above waterline)
Toilets (above waterline)
Toilet fixtures
Toilet paper dispenser
Restroom dispenser
Sink fixture

(Note to EPA: [Bracketed] words & statements are optional unless specified in 40 CFR 156.10)

Restroom fixtures
Cages
Crates
Veterinary surfaces
Food cases
Food trays
Food preparation surfaces
Food prep surfaces
Dish racks
High touch points
Reusable restraints
Exercise equipment
Shared work equipment

(List of **Materials:** Product may be used on objects made from these materials)

Hard plastics
Stainless steel
Laminated counter tops
Laminated table tops
Glazed ceramic tile
Sealed fiberglass
Glass Nonporous flooring material
Glazed porcelain

(General Claims)

See expiration date on bottle
Bactericidal
Disinfectant
Virucidal*

This product is not to be used as a terminal sterilant/high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

EMERGING VIRAL PATHOGENS:

“This product qualifies for emerging viral pathogen claims per the EPA’s ‘Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels’ when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

- Enveloped Viruses
- Large Non-Enveloped Viruses
- Small Non-Enveloped Viruses

| For an emerging viral pathogen that is a/an: | ...follow the direction for use for the following organisms on the label: |
|--|---|
| Enveloped virus | Feline Calicivirus (surrogate for Norovirus) |
| Large, non-enveloped virus | Feline Calicivirus (surrogate for Norovirus) |
| Small, non-enveloped virus | Feline Calicivirus (surrogate for Norovirus) Poliovirus Type 1 |

Acceptable claim language:

Tumult has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, [porous and/or non-porous surfaces]. Therefore, Tumult can be used against [name of emerging virus] when used in accordance with the directions for use against Norovirus (Norwalk virus) and Feline Calicivirus on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

[Name of illness/outbreak] is caused by [name of emerging virus]. Tumult kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against Norovirus (Norwalk virus) and Feline Calicivirus on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [website address] for additional information.”

Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

To Clean & Deodorize

Spray area with this product [product name] [product] until surface is completely wet. Wipe off with a clean damp cloth or sponge.

Quick One Minute Disinfection Action

For one-minute disinfectant activity in the presence of 5% organic soil:

1. Spray area with this product [product name] [product] until surface is completely wet.
2. Allow the product to wet surface for one minute.
3. Wipe off with a clean damp cloth or sponge.

Preliminary cleaning is required for heavily soiled areas.

(Note to EPA: [Bracketed] words & statements are optional unless specified in 40 CFR 156.10)

(**Note to EPA:** These statements to be used when food contact surfaces are included on the label)

Before using this product in food processing areas, all food products and packaging materials must be removed from the room or carefully protected. After use, all food contact surfaces must be thoroughly rinsed with potable water before reuse. Do not use this product to disinfect or clean utensils, glasses, dishes, or cookware.

Special Instructions for Cleaning Prior to Disinfection against Clostridium difficile spores:

Personal Protection: Wear appropriate barrier protection such as gloves, gowns, masks or eye covering.

Cleaning Procedure: Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with a clean cloth, mop, and/or sponge saturated with the disinfectant product. Cleaning is to include vigorous wiping and/or scrubbing, until all visible soil is removed. Special attention is needed for high-touch surfaces. Surfaces in patient rooms are to be cleaned in an appropriate manner, such as from right to left or left to right, on horizontal surfaces, and top to bottom, on vertical surfaces, to minimize spreading of the spores. Restrooms are to be cleaned last. Do not reuse soiled cloths.

Infectious Materials Disposal: Materials used in the cleaning process that may contain feces/wastes are to be disposed of immediately in accordance with local regulations for infectious materials disposal.

Disinfection Procedure: Spray area with [product name] [this product] [product] until surface is completely wet. Allow the product to wet surface for 8 minutes. Wipe off with a clean damp cloth or sponge.

KILLS HIV-1, HBV, AND HCV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1, HBV, AND HCV ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

PERSONAL PROTECTION: When handling items soiled with blood or body fluids, use disposable impervious gloves, gowns, masks, and eye coverings.

CLEANING PROCEDURES: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this product.

CONTACT TIME: Allow surface to remain wet for 30 seconds. For all other organisms, see directions for contact times.

DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids must be autoclaved and disposed of according to local regulations for infectious waste disposal.

(**Note to EPA:** [Bracketed] words & statements are optional unless specified in 40 CFR 156.10)

To Clean and Disinfect in Veterinary Applications:

Use to clean and disinfect hard nonporous surfaces such as floors, walls, counter tops, cages, crates, utensils, kennels, stables, catteries, feeding and watering equipment, etc. Remove all animals and feed from premises, vehicles, and enclosures. Remove all litter and manure from walls, floors and surfaces of facilities occupied or traversed by animals. Empty all feeding and watering equipment. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with [this product] [product] [product name] and let stand for [one] [1] minute. Rinse all surfaces with potable water. Ventilate buildings and other closed spaces. Do not house animals or use equipment until treated surfaces have been allowed to dry. Thoroughly scrub all treated feeding and watering appliances with soap or detergent and rinse with potable water before reuse.

PRECAUTIONARY STATEMENTS

Hazards to humans and domestic animals

CAUTION

Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

FIRST AID

If in Eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. If present, remove contact lenses after the first 5 minutes then continue rinsing eye. Call a poison control center or doctor for further treatment advice.

24 HOUR MEDICAL EMERGENCY NUMBER: 888-314-6171

Have the product container or label with you when calling a poison center or doctor, or going for treatment.

PHYSICAL OR CHEMICAL HAZARDS

Mixing or using this product with gross filth such as feces or urine, ammonia, acids, or other chemicals may release hazardous gases irritating to the eyes, lungs and mucous membranes.

(Note to EPA: The following text will be used on five gallon pails and larger containers only.)

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes streams ponds estuaries oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting agency has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

(Note to EPA: The following text will be used on five gallon pails or less.)

(Note to EPA: [Bracketed] words & statements are optional unless specified in 40 CFR 156.10)

STORAGE AND DISPOSAL

Do not contaminate water food, or feed by storage or disposal.

Pesticide Storage: Store in a cool, dry area inaccessible to children.

Pesticide Disposal: Pesticide wastes may be hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal: Nonrefillable container. Do not reuse or refill container. Triple rinse as follows: Fill container $\frac{1}{4}$ full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

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Container Disposal: Nonrefillable container. Do not reuse or refill container. Triple rinse as follows: Fill container $\frac{1}{4}$ full with water. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn container over onto its other end and tip it back and forth several times. Follow Pesticide Disposal instructions for rinsate disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

[QUESTIONS OR COMMENTS? Call (800) 537-8990]

SPARTAN CHEMICAL COMPANY, INC., 1110 Spartan Drive,
Maumee, Ohio 43537 1-800-537-8990 /www.spartanchemical.com